SUMMONS IN A CIVILA CITIEN V- CLATET CAPE CAPMENT PLEASE, CUVALIDA COUNTRY JESTECTE CENTER

CASE NO. CV12781262

D1 CM

SUMMONS NO. 19299607

ND, OHIO 44113

Rule 4 (B) Ohio

Rules of Civil Procedure

HOPE E. REIMER, EXECUTOR VS

CASE WESTERN RESERVE UNIV. OFFICE OF GEN. COUN. ET

PLAINTIFF

DEFENDANT

SUMMONS

CASE WESTERN RESERVE UNIVERSITY OFFICE OF GENERAL COUNSEL 2040 ADELBERT RD., SUITE 311 CLEVELAND OH 44106-0000

Said answer is required to be served on:



Plantiff's Attorney

JOHN T BULLOCH 134 MIDDLE AVE.

ELYRIA, OH 44035-0000

You have been named defendant in a complaint (copy attached hereto) filed in Cuyahoga County Court of Common Pleas, Cuyahoga County Justice Center, Cleveland, Ohio 44113, by the plaintiff named herein.

You are hereby summoned and required to answer the complaint within 28 days after service of this summons upon you, exclusive of the day of service.

Said answer is required to be served on Plaintiff's Attorney (Address denoted by arrow at left.)

Your answer must also be filed with the court within 3 days after service of said answer on plaintiff's attorney.

If you fail to do so, judgment by default will be rendered against you for the relief demanded in the complaint.

Case has been assigned to Judge:

HOLLIE L GALLAGHER Do not contact judge. Judge's name is given for attorney's reference only.

> GERALD E. FUERST Clerk of the Court of Common Pleas



DATE Apr 30, 2012

COMPLAINT FILED 04/25/2012

CMSN130

Case: 1:12-cv-01475-CAB Doc #: 1-1 Filed: 06/11/12 2 of 16. PageID #: 7 SUMMONS IN A CIVIL ACTION (CLEV _ AND, OHIO 44113

CASE NO. CV12781262

D2 CM

SUMMONS NO. 19299608

Rule 4 (B) Ohio

Rules of Civil Procedure

HOPE E. REIMER, EXECUTOR VS

CASE WESTERN RESERVE UNIV. OFFICE OF GEN. COUN. ET

PLAINTIFF

DEFENDANT

SUMMONS

CASE WESTERN RESERVE UNIVERSITY C/O ELIZABETH J KEEFER, STAT AGT 10900 EUCLID AVENUE ADELBERT HALL, ROOM 311

CLEVELAND OH 44106-0000

Said answer is required to be served on:



Plantiff's Attorney

JOHN T BULLOCH 134 MIDDLE AVE.

ELYRIA, OH 44035-0000

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GERALD E. FUERST Clerk of the Court of Common Pleas



DATE Apr 30, 2012

Deputy

COMPLAINT FILED 04/25/2012



SUMMONS IN A CHIEL ACTION-OCOTURE OF COMMON PLEASIC OBAHOCA COUNTY FUSTION CENTER ND, OHIO 44113 CLEV

CASE NO.

CV12781262

D3 CM

SUMMONS NO. 19299609

Rule 4 (B) Ohio

Rules of Civil Procedure

HOPE E. REIMER, EXECUTOR

VS

CASE WESTERN RESERVE UNIV. OFFICE OF GEN. COUN. ET

DEFENDANT

PLAINTIFF

SUMMONS

UNIVERSITY HOSPITALS CLEVELAND MEDICAL CENTER DBA UNIVERSITY HOSPITALS CASE MEDICAL CENTER OFFICE OF GENERAL COUNSEL 3605 WARRENSVILLE CENTER ROAD MAILSTOP: MSC 9115

SHAKER HTS OH 44122-0000

Said answer is required to be served on:



Plantiff's Attorney

JOHN T BULLOCH 134 MIDDLE AVE:

ELYRIA, OH 44035-0000

You have been named defendant in a complaint (copy attached hereto) filed in Cuyahoga County Court of Common Pleas, Cuyahoga County Justice Center, Cleveland, Ohio 44113, by the plaintiff named herein.

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If you fail to do so, judgment by default will be rendered against you for the relief demanded in the complaint.

Case has been assigned to Judge:

HOLLIE L GALLAGHER

Do not contact judge. Judge's name is given for attorney's reference only.

> GERALD E. FUERST Clerk of the Court of Common Pleas

DATE Apr 30, 2012

COMPLAINT FILED 04/25/2012





SUMMONS IN A COASEA CITION V-COATEF COMMENDE LEAR CUTATIONS A COMPLEX PENTER ND, OHIO 44113

CASE NO. CV12781262

D4 CM

SUMMONS NO. 19299610

Rule 4 (B) Ohio

Rules of Civil Procedure

HOPE E, REIMER, EXECUTOR VS

CASE WESTERN RESERVE UNIV. OFFICE OF GEN. COUN. ET

PLAINTIFF

DEFENDANT

SUMMONS

UNIVERSITY HOSPITALS CLEVELAND MEDICAL CENTER DBA UNIVERSITY HOSPITALS CASE MEDICAL CENTER C/O JANET T MILLER, STAT AGT 3605 WARRENSVILLE CENTER ROAD MAILSTOP: MSC 9110 SHAKER HTS OH 44122-0000

Said answer is required to be served on:



Plantiff's Attorney

JOHN T BULLOCH 134 MIDDLE AVE.

ELYRIA, OH 44035-0000

You have been named defendant in a complaint (copy attached hereto) filed in Cuyahoga County Court of Common Pleas, Cuyahoga County Justice Center, Cleveland, Ohio 44113, by the plaintiff named herein.

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If you fail to do so, judgment by default will be rendered against you for the relief demanded in the complaint.

Case has been assigned to Judge:

HOLLIE L GALLAGHER

Do not contact judge. Judge's name is given for attorney's reference only.



Deputy

DATE Apr 30, 2012

COMPLAINT FILED 04/25/2012



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2012 APR 25 A 10: 54

IN THE COURT OF COMMON PLEAS CUYANOGA COUNTY, OHIO

HOPE E. REIMER, EXECUTOR OF THE) Case No.
ESTATE OF MICHAEL REIMER)
Plaintiff,	Complaint HOLLIE L GALLAGHER CV 12 781262 COMPLAINT COMPLAINT
V.	AFFIDAVIT OF MERIT ATTACHED HERETO
CASE WESTERN RESERVE UNIVERSITY OFFICE OF GENERAL COUNSEL 2040 Adelbert Rd., Suite 311 Cleveland, Ohio 44106))) <u>JURY DEMAND</u>) <u>ENDORSED HEREON</u>
And)
CASE WESTERN RESERVE UNIVERSITY c/o Elizabeth J. Keefer, Statutory Agent 10900 Euclid Avenue Adelbert Hall, Room 311 Cleveland, Ohio 44106	\$ 100 °C DEPOSITED 3024 APR 25 2872
And	SECURE COSTS GERALD E FUERST, Clerk of Courts
UNIVERSITY HOSPITALS CLEVELAND MEDICAL CENTER dba UNIVERSITY HOSPITALS CASE MEDICAL CENTER OFFICE OF GENERAL COUNSEL 3605 Warrensville Center Road Mailstop: MSC 9115 Shaker Heights, OH 44122	PER

CV12781262 73550764

And)
UNIVERSITY HOSPITALS CLEVELAND MEDICAL CENTER dba UNIVERSITY HOSPITALS CASE)))
MEDICAL CENTER c/o Janet T. Miller, Statutory Agent 3605 Warrensville Center Road Mailstop: MSC 9110 Shaker Heights, Ohio 44122)
Defendants.))

Now comes Plaintiff, by and through counsel, and states for her Complaint as follows:

INTRODUCTION

- 1. Hope E. Reimer is the Executor of the Estate of Michael J. Reimer, which has been opened in Cuyahoga County, Ohio and bears case number 2011 EST 0172596. She brings this wrongful death action pursuant to Ohio's Wrongful Death Statute for the exclusive benefit of the beneficiaries of the Estate of Michael J. Reimer, including, but not limited to, Hope E. Reimer, Michelle E. Reimer, Kathryn Lynn Reimer and Christopher Michael Reimer.
- 2. At all times relevant the decedent was a resident in Cuyahoga County, Ohio.
- 3. Case Western Reserve University (hereinafter "CWRU") is an Ohio non-profit corporation. Its stated purpose is to operate a university

- and promote education, instruction and research. Its principal office is located in Cuyahoga County, Ohio.
- 4. University Hospitals Cleveland Medical Center dba University Hospitals Case Medical Center (hereinafter "University Hospitals") is an Ohio non- profit corporation. Its stated purpose is to maintain and operate hospitals and provide medical care through its officers, directors, employees, actual agents, apparent agents and servants. Its principal office is located in Cuyahoga County, Ohio.
- 5. Upon information and belief, there are various agreements, relationships and shared services that exist between CWRU and University Hospitals.
- 6. Both CWRU and University Hospitals engage in research involving human subjects. Such research is guided by various Federal regulations.
- 7. Institutional review boards (hereinafter "IRB") have been established at CWRU and University Hospitals. The primary purpose of each IRB is to protect the rights and welfare of human subjects recruited to participate in research activities conducted under the auspices of each institution.
- 8. Upon information and belief, certain research studies that are conducted by employees of CWRU's Frances Payne Bolton School of

- Nursing are reviewed, modified, approved and monitored by University Hospital's IRB.
- 9. Upon further information and belief, CWRU and University Hospitals are each required to provide financial and other support to University Hospital's IRB. CWRU and University Hospitals are both responsible for the negligent acts or omissions of University Hospital's IRB.
- 10. Upon information and belief, Mary Dolansky, RN, PhD was at all times relevant a professor at the Frances Payne Bolton School of Nursing and an employee of CWRU. CWRU is vicariously liable for the negligence of its employees.
- 11. Upon information and belief, Nicole Ureda was a research associate employed by CWRU. CWRU is vicariously liable for the negligence of its employees.
- 12. Mary Dolansky, R.N., PhD was the principal investigator of a research protocol entitled "Self-management and Cognitive Function in Adults with Cardiovascular Disease: Heart Failure." In order to be approved for inclusion in this study, participants had to objectively demonstrate that they suffered from significant heart failure.
- 13. The study was initially approved by University Hospital's IRB without reservation through April 11, 2011. University Hospital's IRB found this study posed no risk to human subjects and approved the study,

- the consent form, and the method to obtain informed consent of participants.
- 14. The 31 page protocol submitted to the IRB included a short description of a "2-Minute Step Test" that would be administered to participants. The protocol failed to identity any physical or health risk of the 2-Minute Step Test to participants. Further, the consent form, approved by University Hospital's IRB, failed to disclose the inclusion of a 2-Minute Step Test as part of the study and failed to warn participants that they could suffer physical harm as a result of their consent to participate.
- 15. Michael Reimer obtained a flyer promoting participation in the research protocol at issue at his cardiologist's office, Lloyd Greene, M.D. Dr. Greene is an officer, director, employee, agent and/or servant of University Hospitals. The flyer stated that there were no known risks to enrolling in the study. Thereafter, Michael Reimer made application for participation in the study.
- 16. During the evening hours of April 26, 2011 CWRU employee Nicole Ureda presented to Michael Reimer's residence. She provided him with the University Hospital Case Medical Center "Consent for Investigational Studies" relative to the above described research study. The Consent Form failed to disclose that a 2-Minute Step

- Test would be required or that there was any risk of physical injury associated with participating in the study.
- 17. After collecting Michael Reimer's medical history and administering a battery of cognitive tests, Nicole Ureda instructed Michael Reimer on the 2-Minute Step Test.
- 18. Michael Reimer completed the 2-Minute Step Test, and immediately thereafter, suffered a fatal cardiac arrhythmia. He was pronounced dead later that evening.

WRONGFUL DEATH

- 19. Plaintiff incorporates the allegations set forth in paragraphs 1 through 18 of this Complaint as if fully set forth herein.
- 20. Plaintiff brings this wrongful death action pursuant to O.R.C. §2125, Ohio's Wrongful Death Statute, for the exclusive benefit of the next of kin of Plaintiff's Decedent, including, but not limited to those enumerated in paragraph 1 of this Complaint.
- 21. Mary A. Dolansky, R.N., PhD was the principal investigator of the study at issue. She had a duty to design a protocol that did not present unacceptable risks to human subjects and to warn potential subjects of risks inherent to their participation. Her failure to do either was negligent. CWRU is vicariously liable for the acts and omissions of its employees.

- 22. Nicole Ureda failed to recognize that Michael Reimer's 2-Minute Step

 Test should be terminated and failed to properly intervene when

 Michael Reimer suffered a cardiac arrest following the conclusion of
 the test. Her failure constitutes negligence for which CWRU is

 vicariously liable.
- 23. The University Hospital's IRB had a duty, as more fully defined by Federal law, to properly evaluate, approve, modify and monitor the research protocol. Its failure to recognize the risks inherent with the 2-Minute Step Test, to require inclusion of a description of the test, to include all reasonably foreseeable risks in the Consent Form, and to assure that appropriate safeguards were in place to protect human subjects during performance of the 2-Minute Step Test each constitutes negligence for which CWRU and University Hospitals are individually and jointly liable.
- 24. CWRU had a duty to train its employees on the proper administration of the 2-Minute Step Test, including, but not limited to recognizing when the participants were being placed at risk of injury, to terminate the test when appropriate, and to intervene in the event of injury. Its failure to do so was negligent.
- 25. CWRU and University Hospitals also had a duty to assure that appropriate safety precautions were in place to protect human subjects during performance of the 2-Minute Step Test. Their failure

- to do so constitutes negligence for which CWRU and University
 Hospitals are individually and jointly liable.
- 26. The above described negligence of CWRU, and its employees Mary Dolansky, R.N., PhD and Nicole Ureda, and University Hospitals negligence in failing to protect human subjects was a direct and proximate cause of Michael Reimer's injuries and death.
- 27. Plaintiff's Decedent's death was wrongful, as defined by Ohio's Wrongful Death Statute, and occurred as a direct and proximate result of the negligence of the Defendants as set forth above. Plaintiff's Decedent suffered a wrongful death, and the next of kin have suffered, among other things, mental anguish, loss of economic support, loss of perspective inheritance, loss of services, society, comfort, and all other such damages as are enumerated under the Ohio Wrongful Death Statute.
- 28. As a further direct and proximate result of the negligence of the Defendants as set forth above, Plaintiff's Decedent was caused to suffer personal injuries, conscious physical pain and suffering, negligent infliction of severe emotional distress, medical expenses and an untimely death from which compensation is sought.

WHEREFORE, Plaintiff prays for judgment against the Defendants for each Cause of Action in an amount in excess of \$25,000.00, together with interests and costs of this action.

JURY DEMAND

Plaintiffs hereby demand a trial by jury for all issues raised herein.

Respectfully submitted,

The Becker Law Firm

Michael F. Becker (0008298) John T. Bulloch (0055483) Attorneys for Plaintiffs

134 Middle Avenue Elyria, Ohio 44035

Tel: 440-323-7070 Fax: 440-323-1879

e-mail: jbulloch@beckerlawlpa.com

IN THE COURT OF COMMON PLEAS CUYAHOGA COUNTY, OHIO

HOPE E. REIMER, EXECUTOR OF THE ESTATE OF MICHAEL REIMER)	CASE:
Plaintiff,)))	JUDGE:
V .)	AFFIDAVIT OF MERIT OF ALAN FEIT, MD.
CASE WESTERN RESERVE UNIVERSITY, ET AL)	
Defendants.)	

Alan Feit, M.D., being first duly sworn according to law, deposes and states as follows:

- I am a board certified Internist and Cardiologist.
- 2. I am licensed to practice medicine in the State of New York.
- I devote at least 75% of my professional time to the active clinical practice of medicine.

- 4. I am familiar with the proper function and oversight of institutional review boards, including, but not limited to the design, implementation, and ongoing monitoring of investigational studies.
- 5. Based upon my review of the medical records, the research protocol, the consent form, and correspondence surrounding the approval of the research project entitled "Self Management and Cardiac Disease: Heart Failure", it is my professional opinion that the applicable standards of care were breached by Mary A. Dolansky, R.N., PhD, and others in the design of the study protocol and consent form, University Hospitals Institutional Review Board for approving the study protocol and consent form as submitted, Nicole Ureda for failing to terminate Michael Reimer's 2-Minute Step Test and failing to properly resuscitate Michael Reserve University for failing to train its employees in the proper administration, monitoring and intervention during an aerobic test and for failing to ensure the 2-Minute Step Test was conducted under appropriate conditions.
 - 7. It is further my opinion that those breaches in the standards of care caused injury and the untimely death of Michael Reimer.

Further Affiant sayeth naught.	Alan Feit, M.D.
STATE OF NEW YORK KINGS COUNTY NEW YORK)) ss:)
Sworn to before me and s	Notary Public JANET B. McKENZIE Notary Public, State of New York No. 01MCS060578 Qualified in Kings County Commission Expires May 20, 2014